

## **REMARKS**

Consideration and entry of this paper, and reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the remarks herein, which place the application in condition for allowance, or in better condition for appeal.

### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 25, 27-32, 34-44, and 47 are pending. Claims 25 and 34 have been amended. Support for the amended claims can be found in the specification and claims as originally filed (see e.g., paragraph 0050 of the published application). No new matter has been introduced.

It is respectfully submitted that the claims, herewith and as originally presented, were in full compliance with the requirements of 35 U.S.C. § 112. It is respectfully submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112, but rather that these amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Applicants note with appreciation that claims 43 and 44 are allowed.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

### **II. THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION) ARE OVERCOME**

Claims 25, 27-32, 34-42, and 47 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims are alleged to contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

With respect to claim 25 (and claims dependent thereon), the Examiner contends that it is unclear to which nucleotides the nucleotides 324 to 488 correspond. In this regard, the Examiner contends that the instant claims are not limited to a specific sequence which defines the nucleotide structure and that there is no clear standard for numbering the adenoviral subtype 5 genome (see discussion below regarding the rejections under 35 U.S.C. § 112, second paragraph).

Contrary to the Examiner's contention, there *is* a standard numbering for the adenoviral subtype 5 genome. The specification explicitly teaches at paragraph 0270 of the published application that "[a]ny patents or publications mentioned in this specification are indicative of the levels of those skilled in the art to which the invention pertains." Attached hereto as Exhibit A is the publication by He et al., "A simplified system for generating recombinant adenoviruses", Proc. Natl. Acad. Sci. USA, 95:2509-2514 (1998), which is explicitly mentioned in Example 13 (see e.g., paragraph 0182 of the published application) and incorporated by reference in the specification. He et al. was made of record in the Information Disclosure Statement filed October 7, 2004 and refers to human adenovirus subtype 5 and to deletion of specific nucleotides within this genome in the construction of their recombinant adenoviruses. In particular, He et al. notes that nucleotides 1-3,533 of the human Ad5 *encompass the E1 genes* (see page 2510, third full paragraph). (Emphasis added).

Further, He et al. notes that "[d]ecades of study of adenovirus biology have resulted in a detailed picture of the viral life cycle and the functions of the majority of viral proteins...The genome of the most commonly used human adenovirus (serotype 5) consists of a linear, 36-kb, double-stranded DNA molecule" (see page 2509, third full paragraph). Exhibits B and C attached hereto detail the GenBank Accession Number entry corresponding to the nucleic acid sequence for the human adenoviral subtype 5 genome and a chapter from a textbook on adenoviruses. As detailed in Exhibit C (see e.g., the paragraph bridging pages 40-41, the first full paragraph and beginning of the third paragraph of page 43, the first paragraph in Section A on page 49, and the structure of the Ad5 genome on page 97), the human adenoviral subtype 5 (hAd5) genome is numbered from left to right according to transcription of the r-strand starting from the left inverted terminal repeat proximal to the E1A gene region and ending with the right side inverted terminal repeat distal to the E4 gene region. Thus, further to the instant specification and references cited therein, the human adenovirus subtype 5 nucleic acid sequence and numbering corresponding thereto were well known to one of ordinary skill in the art at the time of filing of the instant application. Nonetheless, the pending claims have been amended to further clarify that nucleotides 324 to 488 of the human adenoviral subtype 5 genome correspond to a region of the E1A promoter of the human adenoviral subtype 5 genome.

Accordingly, in view of the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph are respectfully requested.

### III. THE REJECTIONS UNDER

#### **35 U.S.C. § 112, SECOND PARAGRAPH ARE OVERCOME**

Claims 25, 27-32, 34-42, and 47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner alleges that it is unclear to which nucleotides the nucleotides 324 to 488 refer and that there is no clear standard for numbering the adenoviral subtype 5 genome. Further to the arguments presented above, Applicants point out that there *is* a standard numbering for the adenoviral subtype 5 genome (see e.g., Exhibits A-C attached hereto). By the time of the instant application's filing, the human adenoviral subtype 5 nucleic acid sequence and numbering corresponding thereto were well known to one of ordinary skill in the art. Nonetheless, the pending claims have been amended to further clarify that nucleotides 324 to 488 of the human adenoviral subtype 5 genome correspond to a region of the E1A promoter of the human adenoviral subtype 5 genome.

Accordingly, in view of the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph are respectfully requested.

**REQUEST FOR INTERVIEW**

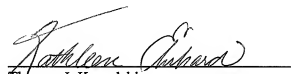
If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

For the reasons stated above, Applicants respectfully request a favorable reconsideration of the application, consideration and entry of this paper, reconsideration and withdrawal of the rejections of the pending claims, and prompt issuance of a Notice of Allowance. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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